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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/702,459  | 11/07/2003  | Mitsuhiro Okuda      | 61352-058           | 9724             |
| 7590  | 02/14/2005  |                      |                     | EXAMINER         |
| Michael E. Fogarty<br>McDERMOTT, WILL & EMERY<br>600 13th Street, N.W.<br>Washington, DC 20005-3096 |             |                      | VANIK, DAVID L      |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1615                |                  |

DATE MAILED: 02/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/702,459             | OKUDA MITSUHIRO     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | David L. Vanik         | 1615                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply-**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-15 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-15 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____ .   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/23/2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: ____ .                                   |

**DETAILED ACTION**

Receipt is acknowledged of the applicant's Oath or Declaration filed on 4/23/2004. Receipt is also acknowledged of applicant's Information Disclosure Statement filed on 6/23/2004.

***Priority***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (b) as follows: Applicant failed to provide an English translation of foreign applications JP 2002-275598 and JP 2003-105676. As such, the priority date of the instant application is interpreted as being 9/17/2003.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-5, 7-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Okuda et al (Biotechnol. Bioeng. 2003 Oct 20;84(2):187-94).

Okuda et al disclose a nanoparticle comprising a metal ion compound that is formed in the cavity of a protein (abstract). A method for producing said nanoparticle is also disclosed (abstract and pages 188-192). According to Okuda et al., the method of producing said nanoparticle comprises incubating a protein, apoferritin, in a nickel or chromium solution containing carbon dioxide (abstract). It is also advantageous to add other chemicals to the solution, such as sodium carbonate (page 192) and ammonium iron sulfate (page 190). The pH of the solution can be maintained at a pH of 8.65 (abstract). Other values pH values, specifically between pH 8 and 9, can be used to prepare the nanoparticle (page 189-190).

Claims 14 and 15 are product-by-process claims. As such, claims 14 and 15 will be treated as product claims and not as method claims. By disclosing a nanoparticle comprising a metal ion compound that is formed in the cavity of a protein, the composition advanced by Okuda et al anticipates the instant claims 14 and 15 (abstract).

Claims 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,690,903 ('903).

Claims 14 and 15 are product-by-process claims. As such, claims 14 and 15 will be treated as product claims and not as method claims. By disclosing a nanoparticle comprising a metal ion compound that is formed in the cavity of a protein, the composition advanced by '903 anticipates the instant claims 14 and 15 (column 2, line 62 – column 3, line 3 and Figures 1-11).

Claims 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/22942 ('942).

Claims 14 and 15 are product-by-process claims. As such, claims 14 and 15 will be treated as product claims and not as method claims. By disclosing a nanoparticle comprising a metal ion compound that is formed in the cavity of a protein, the composition advanced by '942 anticipates the instant claims 14 and 15 (page 5, lines 6-27).

Claims 1-3, 5-11, 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,304,382 ('382).

'382 disclose nanoparticles comprising an apoferritin protein shell packed with polyvalent metals, such as ammonium, chromium, and copper (column 4, line 54 – column 5, line 15). Other chemical entities, such as carbonate and mixtures of hydroxides and oxides can also be present in the apoferritin protein shell (column 5,

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lines 7-15). Said nanoparticles can be prepared by combining the apoferritin protein shell together with metal ions or other chemical entities such as carbonate and mixtures of hydroxides and oxides in a solution (column 6, lines 51-67). The solution can be buffered with compounds such as HEPES or ammonium acetate (column 6, lines 51-55). According to '382, choice of the pH solution is influenced by the solubility of the material to be incorporated into apoferritin (column 6, lines 64-67). One of ordinary skill in the art at the time the invention was made would have the capacity to adjust the pH of the solution based on the specific application.

Claims 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,358,722 ('722).

Claims 14 and 15 are product-by-process claims. As such, claims 14 and 15 will be treated as product claims and not as method claims. By disclosing a nanoparticle comprising a metal ion compound that is formed in the cavity of a protein, the composition advanced by '722 anticipates the instant claims 14 and 15 (claims 1-5).

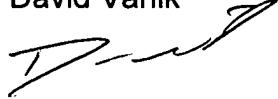
***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik



2/7/05



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